UNITED STATES DEPARTMENT OF COMMERCE
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VB

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/428,122 | 10/27/99 | MURDIN A | 19721-007-(P |

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| EXAMINER | |
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| DEVI,S | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1645 | 3 |

DATE MAILED: 07/12/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/428,122 | Murdin et al. |
| **Examiner** | **Group Art Unit** |
| S. Devi, Ph.D. | 1645 |

☒ Responsive to communication(s) filed on *10/27/1999.*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *one* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) *1-37* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-37* are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

**Restriction / Election**

**1)** Claims 1-37 are under prosecution. Claim 27 is improperly dependent from claim 21, which is drawn to a polypeptide rather than a polynucleotide probe reagent. Currently, for the purpose of the restriction requirement set forth below, it is assumed that claim 27 depends from claim 25, which is drawn to a polynucleotide probe reagent. Clarification/correction is requested.

**2)** **Please Note**: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your election responses. The Fax number is 703-305-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

**3)** Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 10-14, 16-19, 25 and 26, drawn to a polynucleotide having a sequence of SEQ ID NO: 1, an expression cassette comprising the polynucleotide, an expression and a vaccine vector and a host cell comprising the same, and a polynucleotide probe reagent, classified in class 536, subclass 23.1.

II. Claims 5-9 and 21-23, drawn to a polypeptide having SEQ ID NO: 2 and a pharmaceutical composition comprising the same, classified in class 530, subclass 350.

III. Claim 15, drawn to a method for producing a recombinant polypeptide having SEQ ID NO: 2 by culturing a host cell comprising an expression vector, classified in class 435, subclass 69.1.

IV. Claim 20, drawn to a method for inducing an immune response in a mammal by administering a vaccine vector comprising an expression vector, classified in class 514, subclass 44.

V. Claim 24, drawn to a method for inducing an immune response in a mammal by administering a composition comprising a polypeptide having a sequence that is 75% homologous to SEQ ID NO: 2, classified in class 424, subclass 263.1.

VI. Claims 27 and 28, drawn to a method for detecting the presence of *Chlamydia* in a sample using a polynucleotide probe reagent, classified in class 435, subclass 6.

VII. Claims 29-32, drawn to a method for detecting the presence of *Chlamydia* by contacting a sample with an antibody that binds to the polypeptide of SEQ ID NO: 2, classified in class 435, subclass 7.1.

VIII. Claims 33-36, drawn to an affinity chromatography method for purifying a polypeptide having SEQ ID NO: 2 by contacting a sample containing the polypeptide with an antibody, classified in class 435, subclass 272.

IX. Claim 37, drawn to an antibody that binds to a polypeptide having a sequence that is 75% homologous to SEQ ID NO: 2, classified in class 530, subclass 387.1.

**4)** Inventions I through IX are distinct from one another. Inventions I, II and IX are drawn to distinct products: a polynucleotide sequence and a host cell, a polypeptide sequence and an antibody. These products are distinct from one another structurally, physicochemically, functionally, immunologically and/or biologically. The polypeptide of invention II can be produced without using the nucleotide sequence of invention I, for example, by chemical synthesis.

Inventions III, IV, V, VI, VII and VIII are directed to independent and distinct methods, which differ from one another in method steps, parameters and reagents or compositions used, and ultimate goals accomplished.

Invention I and inventions III and IV are related as product and processes of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the host cell of invention I can be used in a materially different process, for example, as a source of coating antigen in an *in vitro* diagnostic assay to measure specific antibodies.

Inventions I and VI are related as product and processes of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the method for detecting *Chlamydia* in a sample can be practiced with another materially different product, such as a *Chlamydia*-specific antibody.

Inventions II and V are related as product and processes of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the polypeptide of invention II can be used in a materially different process, for example, as a source of coating antigen in an *in vitro* diagnostic assay to measure polypeptide-specific antibodies.

Invention IX and inventions VII and VIII are related as product and processes of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the antibody of invention IX can be used in a materially different process, for example, as source of immunogen in the generation of anti-idiotypic antibodies.

The product of invention I is not required to practice the methods of inventions V, VII and VIII. The product of invention II is not required to practice the methods of inventions III, IV, VI, VII and VIII. Similarly, the product of invention IX is not required to practice the method of inventions III, IV, V and VI.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification/subclassification and divergent subject matter, and since a search performed for one would not be co-extensive for the other, restriction for examination purposes as indicated is proper.

**5)** Applicants are advised that the response to this requirement to be complete must include

an election of the invention to be examined even though the requirement be traversed (37 C.F.R 1.143).

**6)** Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition under C.F.R 1.48(b) and by the fee required under 37 C.F.R 1.17(h).

**7)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. The Examiner can normally be reached on Monday to Friday from 7.45 a.m. to 4.15 p.m. A telephone message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynnette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SD

S. Devi
Patent Examiner
July 2000

# RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

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IN COMPLIANCE WITH 1096 OG 30, THE FILING DATE ACCORDED EACH OFFICIAL FAX TRANSMISSION WILL BE DETERMINED BY THE FAX MACHINE DATE STAMP FOUND ON THE LAST PAGE OF THE TRANSMISSION, UNLESS THAT DATE IS A SATURDAY, SUNDAY, OR FEDERAL HOLIDAY WITHIN THE DISTRICT OF COLUMBIA, IN WHICH CASE THE OFFICIAL DATE OF RECEIPT WILL BE THE NEXT BUSINESS DAY.